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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,816	Applicant(s) BURTON ET AL.	
	Examiner KAREN E. TOTH	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73, 78 and 79 is/are pending in the application.
- 4a) Of the above claim(s) 1-54 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 78 is/are allowed.
- 6) ☒ Claim(s) 55-73 and 79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/22/07</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

2. Claims 61 and 62 are objected to because of the following informalities:
The claims are identical. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 79 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not disclose, at any point, performing a weighting calculation based on a mediation process.

Claim Rejections - 35 USC § 103

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5. Claims 55, 56, 58-60, 66-69, 71, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over John (US Patent 6385486) in view of Barnea (US Patent 6117075).

Regarding claims 55, 56, 58, 60, and 66, John discloses an apparatus for determining a patient's level of consciousness comprising means for acquiring at least one continuous biosignal (EEG) using at least one sensor electrode (column 5, lines 47-49), means for stimulating at least one evoked potential signal in the patient (element 16), means for acquiring at least one evoked potential signal using at least one sensor (column 6, lines 54-60), and means for calculating an index from each acquired biosignal (element 40; column 6, lines 23-25; column 9, lines 47-54; column 11, lines 5-20 and 27-29; column 12, lines 53-58) and selecting one of the indices to represent the patient's state of consciousness (column 3, lines 12-18; column 4, lines 15-17; column 8, line 55 to column 9 line 54), where the means for acquiring the biosignal and evoked potential signal utilize a common electrode sensor means (column 7, lines 4-7). John does not disclose selecting at least one of at least two indices representing the subject's state of consciousness, each being derived from a different transformation of signal data.

Barnea teaches a system for monitoring a patient's state of consciousness that generates a plurality of indices representing the patient's state of consciousness, each being a function of a different signal transformation, and using one as the consciousness representation (column 6, lines 30-49), in order to generate an accurate representation of the patient's state.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system John and used the system to generate at least two differently derived indices of the patient's state, as taught by Barnea, in order to generate an accurate representation of the patient's state.

Regarding claim 59, John further discloses means for deriving the evoked potential signal from the EEG signal (element 40).

Regarding claims 67-69, John further discloses generating an evoked potential stimulus that is an auditory signal which induces a steady state response signal (element 17B; column 3, lines 38-41; column 8, lines 42-44; column 9, lines 26-28; column 12, lines 23-26).

Regarding claims 71-72, John further discloses the means for inducing an auditory evoked potential response signal including means for producing an evoked response paradigm such as a click stimulus or a response at spaced intervals within a click stimulus, where the stimulus is generated according to a predetermined sequence determined by means incorporated within the apparatus (column 6, lines 50-54; column 8, lines 42-44; column 12, lines 14-52).

6. Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Barnea, as applied to claims 55, 56, 58-60, 66-69, 71, and 72 above, and further in view of Loos (US Patent 5782874).

John in view of Barnea discloses all the elements of the claimed invention, as described above, except for the biosignal being a muscular activation signal measuring eyelid movement. Loos teaches a system for monitoring a patient's

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state of consciousness in response to a stimulating signal that measures eyelid movement biosignals (column 11, lines 23-31, 33-36, 41-63; column 12, lines 11-13), in order to assess the patient's response to the stimulating signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John in view of Barnea using muscular activation signals to measure eyelid movement as the biosignal, as taught by Loos, in order to assess the patient's response to applied evoked potentials.

7. Claims 61, 62 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Barnea, as applied to claims 55, 56, 58-60, 66-69, 71, and 72 above, and further in view of Ennen (US Patent 6217627).

Regarding claims 61 and 62, John in view of Barnea discloses all the elements of the claimed invention, as described above, except for monitoring the signals for signal quality. Ennen teaches a system for obtaining biosignals from a patient, where the signals are regularly monitored for signal quality (column 3 line 63 to column 4 line 2; column 4, lines 20-24 and 59-61), in order to ensure the accuracy of the signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John in view of Barnea with means for monitoring signal quality, as taught by Ennen, in order to ensure the accuracy of the captured data.

Regarding claim 70, John in view of Barnea discloses all the elements of the claimed invention, as described above, except for the system comprising means for displaying the functional or operational status of a sensor. Ennen

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teaches a system for obtaining biosignals from a patient comprising means for displaying the functional or operational status of its sensors (elements 42 and 43; column 5, lines 10-13; column 7, lines 35-49), in order to ensure that the captured data is accurate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John in view of Barnea with means for displaying the functional or operational status of the sensor, as taught by Ennen, in order to ensure the accuracy of the captured data.

8. Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Barnea, as applied to claims 55, 56, 58-60, 66-69, 71, and 72 above, and further in view of Lahteenmaki (US Patent 6728564).

Regarding claim 63, John in view of Barnea discloses all the elements of the claimed invention, as described above, except for the apparatus using a disposable or semi-disposable sensor. Lahteenmaki teaches a consciousness-monitoring system for measuring biosignals using disposable sensors (column 3, lines 5-7), in order to increase the system's sterility. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John in view of Barnea with disposable sensors, as taught by Lahteenmaki, in order to ensure the system's cleanliness.

John further discloses that the system may be a portable system for monitoring consciousness where the system's sensor (element 100) includes

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means for activating a battery (since the battery is contained within element 100 – column 13, lines 8-13).

9. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Barnea and Lahteenmaki, as applied to claims 63 and 64 above, and further in view of Semler (US Patent Application Publication 2003/0069510).

John in view of Barnea and Lahteenmaki discloses all the elements of the claimed invention, as described above, except for the means for activating the energy source including the packaging of the energy source.

Semler teaches a disposable sensor system that includes an activatable energy source (battery) where the means for activation is included in the packaging (paragraph [0034]), in order to allow selective activation of the unit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John in view of Barnea and Lahteenmaki with means for activating the energy sources included in its packaging, as taught by Semler, in order to allow easy and selective activation of the source.

10. Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Barnea, as applied to claims 55, 56, 58-60, 66-69, 71, and 72 above, and further in view of Ennen.

John in view of Barnea discloses all the elements of the current invention, as described above, except for the system comprising means for alerting an

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operator to a sensor's status. Ennen teaches a system for obtaining biosignals from a patient comprising means for displaying the functional or operational status of its sensors (elements 42 and 43; column 5, lines 10-13; column 7, lines 35-49), in order to ensure that the captured data is accurate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John in view of Barnea with means for displaying the functional or operational status of the sensor, as taught by Ennen, in order to ensure the accuracy of the captured data.

Allowable Subject Matter

11. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the method of claim 78, including, *inter-alia*,

Response to Arguments

12. Applicant's arguments filed 22 August 2007 have been fully considered but they are not persuasive.

Applicant's arguments with respect to John have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument that Loos is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with

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which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Loos is reasonably pertinent to the problem motivating the present application, since it is directed to monitoring a patient's state of consciousness.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5320109 to Chamoun, which discloses similar inventions.

US Patent 6966650 to Hu, which discloses similar inventions.

US Patent 5263489 to Johnson, which discloses similar inventions.

US Patent Application Publication 2003/0181821 to Greenwald, which discloses similar inventions.

US Patent Application Publication 2004/0243017 to Causevic, which discloses similar inventions.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735